DEC 1 3 2001

Índigo® OPTIMA Laser System
510(k) Summary of Safety & Effectiveness

Company
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242

Contact
Linda G. Hill
Regulatory Affairs Manager

Date Prepared
August 21, 2001

Device Name
Trade Name: Índigo® OPTIMA Laser System
Classification Name: Laser powered surgical instrument

Predicate Device
The Índigo OPTIMA Laser System is substantially equivalent to the current Índigo LaserOptic® Treatment System cleared by FDA on December 23, 1997 (K963969), as well as the following submissions:

- K954195, cleared January 25, 1996, Índigo Portable Laser System Model IDL 830 and Índigo Fiberoptics
- K955758, cleared February 27, 1996, Índigo Portable Laser System with Temperature Feedback Model 830e
- K963081, cleared February 21, 1997, Índigo Models IDL 830 and IDL 830e Laser Systems
- K990851, cleared March 30, 1999, Índigo Diffuser-Tip Fiberoptic with Temperature Sensing Option
- K003952, cleared March 16, 2001, Índigo LaserOptic Treatment System
- K003953, cleared March 16, 2001, Índigo Diffuser-Tip Fiberoptic with Temperature Sensing Option

Device Description

The Índigo® OPTIMA Laser System consists of a treatment diode laser, fiberoptic energy delivery devices, a footswitch, and an optional cart with printer. The treatment laser allows delivery of controlled doses of laser energy in wavelengths between 800 and 850 nanometers (nm). When used with the OPTIMA Diffuser-Tip Fiberoptic, this laser energy is diffused radially at 360° to the affected tissue to provide interstitial thermotherapy (ITT), or interstitial laser coagulation (ILC). When used with the OPTIMA Bare-Tip or cutting fiber, the laser beam directly contacts the tissue to provide incision, excision, ablation, or coagulation of tissues with hemostasis. Both the OPTIMA Diffuser-Tip and Bare-Tip Fiberoptics are designed to deliver

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energy from the Índigo OPTIMA diode laser **only** and bear unique, proximal connectors to the OPTIMA laser. The fiberoptics (fibers) are designed to be sterile, single patient use, disposable devices. In addition, there are several accessories to the laser system including laser goggles, a traveling case, and fiberoptic instruments for servicing and demonstration (for sales representatives only and **not** for human use).

Intended Use

The Índigo OPTIMA Laser System,as a surgical instrument, is intended to be used in the non-contact mode to photocoagulate, vaporize/ablate soft tissue (muscle, connective tissue, organ), for cutting, excision, incision, and for coagulation of soft tissue in the contact mode (open/closed) surgical procedures. When used with bare fiberoptics, the Índigo diode laser can be used for the excision of external tumors and lesions, complete and partial resection of internal organs, treatment of tumors and lesions, skin incision and tissue dissection and ablation. The Diffuser-Tip Fiberoptic is intended for the safe and effective treatment of Benign Prostatic Hyperplasia (BPH).

Comparison of Technological Characteristics

The Índigo OPTIMA Laser System is a modification of the currently marketed Índigo LaserOptic Treatment System. While it represents a refinement to the predicate system, the overall technology and the intended use of the two systems are the same. Both the predicate and the modified systems are designed to treat Benign Prostatic Hyperplasia (BPH) when used with the Diffuser-Tip Fiber. and as a general surgical tool for cutting tissue when used with the Bare-Tip Fiber. The design modifications include upgrades to the software and electronic components, as well as modifications to the fibers to permit use with smaller cystoscopes, having a working channel of 5 FR. New accessories to the system include a laser cart, providing storage and mobility, and a printer to record procedure data for patient records.

The OPTIMA laser unit contains two, diode lasers that convert electrical energy to optical energy in narrow wavelength bands. The treatment laser produces red light in the near infra-red spectrum with a wavelength of 800-850 nm and is classified as a Class IV laser by the U.S. Center for Devices and Radiological Health (CDRH) and according to DIN VDE 0837. The marker laser produces light in the visible light range (approximately 633 nm) and is classified as a Class II laser by CDRH. This is identical to the predicate laser system.

Performance Data

Preclinical testing was performed to ensure that the laser system performs as intended when used according to the instructions for use. Bench testing has indicated that the system demonstrates satisfactory performance for its intended applications. Electrical safety and electromagnetic compatibility have been demonstrated and are certified by VDE Testing and Certification Institute. The Índigo OPTIMA System bears the CSA International label for UL-2601-1, CSA 601.1, and IEC 60601-1.

The Índigo OPTIMA Laser System meets U.S. Federal Safety and Performance Standards for light emitting products (21 CFR 1040.10/11).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ethicon Endo-Surgery
c/o Mr. Mark Job
510(k) Program Manager
TÜV Product Service
1775 Old Highway 8
New Brighton, Minnesota 55112-1891

Re: K013493
Trade/Device Name: Índigo® OPTIMA Laser System
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: December 4, 2001
Received: December 5, 2001

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K013493

Device Name : Índigo® OPTIMA Laser System

Indications for Use :

The Índigo OPTIMA Laser System with Diffuser-Tip Fiberoptic is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostates with median and/or lateral lobes ranging in total volume from 20-85 cc; and for general surgery, general urological, general gynecological and general gastroenterological procedures; and coagulative necrosis and interstitial laser coagulation of soft tissues such as tumors and fibroids.

The Índigo OPTIMA Laser System, when used in conjunction with the Bare-Tip Fiberoptic, is indicated for the incision, excision, and ablation or coagulation of tissues with hemostasis during general surgery, and general gastroenterological and urological procedures, including those involving urethral strictures, bladder neck contractures, and condylomata.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of General Restorative Devices

510(k) number_____

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

Susan Walker
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

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